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Reimbursement Issues with Hormonal Therapies for Prostate Cancer

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Abstract

Reimbursement issues surrounding the treatment of prostate cancer with hormonal therapies have changed dramatically in the past 2 years. The ultimate goal for urologists when making treatment decisions regarding LHRH agonist use is to continue to provide hassle-free, complete care for patients, including whatever medications they need. This is still fully possible under the new rules without sacrificing the opportunity to profit from office-based administration of injectable medications.

Key words: LHRH agonists, Average sale price, Average wholesale price, Modifier –25

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Reimbursement issues surrounding the treatment of prostate cancer with hormonal therapies have changed dramatically in the past 2 years. As one office manager stated, the "present is not like it used to be. The Christmas candy is gone." These changes were mandated by the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003.[1] More recently, the Centers for Medicare and Medicaid Services (CMS) published, in the *Federal Register*, the final rules for revisions to payment policies under the physician fee schedule for the 2005 calendar year.[2]

According to Medicare statistics, urologists received approximately 37% of their total 2004 Medicare revenues from drugs and 60% from all other services. Medicare has estimated that the change in payment to physicians for drugs will decrease income to urologists from prescription of LHRH agonists by 38%. The overall impact on income will be a decrease of 14%. In 2004, this profit center accounted for up to 40% of the take-home pay for some urologists. Urologists are expected to lose a majority of that income, approximately $60,000 for the average practitioner.

The payment for chemotherapeutic injections has decreased more than originally anticipated. The national average payment to physicians for a single injection has dropped from $64.07 to $36.62.[3] A committee formed by the American Medical Association (AMA), at the request of CMS, reevaluated injections and other treatment modalities for cancer, and their recommendations ultimately led to changes in many delivery codes as well as the addition of new codes. CMS changed the payments as well.

Overall Impact of MMA 2003

- Average annual decrease: $60,000.00 per urologist
- Some urologists: ↓ 30% net income
- Continuously changing market
- Current profits exceed 6%

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Reimbursement

The MMA 2003 changed the way physicians are paid for injectable drugs administered in the office. Before the new rules, urologists were paid a percentage of the average wholesale price (AWP) (95% of AWP in 2003, between 80% and 85% of AWP in 2004).[3] In 2005, urologists are being paid 106% based on average sale price (ASP) (not 106% of their purchase price for the drug).[4] Although there is still room for profit in this model, the margin is not as large.

What is the difference between AWP and ASP? AWP is the recommended wholesale price provided by the pharmaceutical company for each drug.[3] ASP is calculated by the pharmaceutical company, on a quarterly basis, using actual sales information and detailed, standardized rules and formulas. All drug sales, with a few exceptions including sales to Medicaid, the government, and a few other specific categories, are included in ASP calculations. All sales to physicians, purchasing groups, pharmacists, wholesalers, including all volume, cash, or other discounts are also included. After ASP figures are determined by the manufacturer (manufacturer's ASP),[4] CMS will average all manufacturers' ASPs charged under a single "J" code, according to their respective volumes, to determine an ASP for the code. For example, the ASP for luprolide acetates, Lupron Depot® (TAP Pharmaceutical Products, Inc., Lake Forest, IL) and Eligard® (sanofi-aventis, Paris, France) will be averaged to develop a single ASP for the Healthcare Common Procedure Code (HCPC) J9217.[4]

Medicare carriers in each state decide whether to pay for the drugs using the least costly alternative (LCA) methodology or not. The LCA methodology (equal payment for drugs under different J codes, that have been determined by Medicare to be "medically equivalent," [eg, Lupron, Eligard [J9217], and Zoladex® [goserelin acetate, AstraZeneca Pharmaceuticals, LP, Wilmington, DE] [J9202]) would result in a third calculation. The lower ASP of the two J codes will be used to determine the payment for all 3 of these Medicare-deemed medically equivalent drugs.[5] Currently, all but 5 states (Wisconsin, Illinois, Michigan, Minnesota, and Montana) have adopted the LCA payment method. In addition, Utah has rescinded LCA payment methods for 6 months, pending final ruling.

The final Medicare payment schedule for the first quarter of 2005 was calculated using actual third quarter 2004 ASP data from the manufacturers.[7] The payment as published for J9217 is $253.13 for 2005, higher than was widely anticipated. As stated above, payment will be made at 106% of the calculations for actual ASP, not on the price paid. The payments will change quarterly based on the changes in reported ASPs. If a given manufacturer sells the drug at a price lower than ASP and a physician buys from that company, the physician will realize a greater profit. However, purchase of the less expensive drug will contribute to a drop in ASP in the next quarter. If a second manufacturer lowers its price to compete with the first company, the ASP will be even lower the following quarter.

Practice Issues

The ultimate goal for urologists when making treatment decisions regarding LHRH agonist use is to continue to provide hassle-free, complete care for patients, including whatever medications they need. With the decrease in profits resulting from these new rules, urologists will need to be selective when contracting with suppliers of LHRH agonist drugs. They must also be mindful of the high cost of maintaining inventory, loss of money from poor insurance-coverage information, or lack of copayment collection, which could be financially disastrous in this new setting.[6]

Solutions

Contracts financially unfavorable to the physician must be avoided. Urologists should continue to get the best price they can for the drug most appropriate for their patients, be sure their contract price is at ASP or below, and be aware that the payment may decrease each quarter. The ability to adjust purchasing contracts to accommodate these changes is optimal.

CMS clearly believes that physicians should continue to treat patients with the appropriate drug for their condition but will watch closely for major changes, including those in the frequency of injections. In particular, they have advised against shifting a significant number of patients from injection-based therapies to administration via implants prior to the end of 2005. It is important to thoroughly document any changes made in the treatment regimen of each patient.[4]

Steps to Maintaining Profits

- Minimize or eliminate inventory cost
- Contingency contract
- No free drugs
  - Diligent insurance review
  - Refer for assistance
- Continue to buy drugs and Rx pts

Injections

Medicare payments for injectable therapies increased significantly in 2004.[3] Subcutaneous or intramuscular (IM) chemotherapy administration (96400), for example, was reimbursed at approximately $64.00 per. For 2005, the injection code has changed for all states. The new code is G0356 and the national payment is $36.62. Physicians can charge for Evaluation and Management (E&M) codes at the same visit, except for 99211, where modifier −25 is needed, as discussed below.

Office Visits

MMA 2003 changed the rules, beginning in 2004, for charging an E&M service on the same day as a chemotherapeutic administration (such as 96400, IM or subcutaneous injection). One can no longer charge a 99211 first-level established patient code (commonly called "the nursing code") on the same day that a chemotherapeutic administration such as 96400 has been charged. However, if the urologist sees a patient and provides a service that qualifies for the use of a modifier −25, then a higher-level 99213, 99214, or 99215 service code can be charged by attaching modifier −25 to the appropriate number. Physicians can also charge a consult or new patient code with modifier −25.[3]

Modifier −25

The correct use of modifier −25 by both payers and providers has again become a topic of some discussion.[7] Due in part to the filing of lawsuits by several medical societies against payers for wrongfully denied payments and 2 resultant settlements, with Aetna Inc. and Cigna HealthCare, the use of modifier −25 is on the rise. Unfortunately, the usage and recognition of modifier −25 is still somewhat variable and can frustrate both the provider and the payer.[8]

First, the definition and intended use of the modifier must be reviewed. The American Medical Association Current Procedural Terminology (CPT®) 2004 lists the definition of modifier −25 as a "significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service."[9] As indicated within the CPT coding manual, the modifier is to be used to indicate that an E&M service, which is significant and clearly separate from other services, was provided on the same day. The definition further indicates that the E&M service is clearly beyond and separate from that which is provided normally as pre- or postoperative care for any global service provided on the same day. The CPT manual also states that a separate problem or diagnosis is not required to distinguish a separate or significant E&M service.

In terms of billing, the modifier −25 is used to indicate that E&M service, fitting the listed definition and supported by clear documentation, is payable on the same date as the injection procedure. Many private payers and Medicare will recognize the modifier −25 as was intended by CPT and will pay for those E&M services for which modifier −25 is used appropriately.

The key to undisputed payment is thorough documentation of medically necessary services and of E&M services that are clearly separate from the procedure(s) provided on the same day. Further, physicians should make sure the E&M note is physically separate from the service documentation. The E&M documentation does not have to be on a separate page from the documentation for the injection. However, it should be separated by line spacing and be self-contained.

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2006 and Beyond

In 2006, physicians will be paid 106% of ASP for injectable drugs or they will have the option of buying their drugs from a contracting agent who will deliver the drugs to the office. The decision is

one of all or nothing. If physicians choose to continue buying drugs, then they must buy all of their drugs. If they choose to use an acquisition agent, then they must buy all drugs through that agency. Making this choice will alleviate all charges for drugs to Medicare and will eliminate any income for storing or handling the drug. However, final regulations have not been published and the pros and cons of this arrangement are not yet clear.[5]

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Summary

In summary, physicians should be prepared for an initial decrease in income and in 2005, plan to delay contracting for purchased drugs until all options and the exact amount to be paid by Medicare are known, automate documentation and billing, code correctly, and prepare for the resurgence of Medicare HMOs. Fortunately, the future is brighter than the projections of doom and gloom previously suggested for 2005. Systems automation and improved data will improve efficiency, thereby increasing income in a number of ways.

Overall Outlook for Urologists

- Continue to buy low, sell high
- Selective contingency contracting
- Develop new profit centers
- Improve business practices
  - Automated processes
  - Improved data for decision-making
- Back to the basics—GPC

Main Points

- The Medicare Prescription Drug Improvement and Modernization Act of 2003 has negatively impacted the income of urologists and will continue to do so through 2005.
- In the past, urologists have been paid a percentage of the average wholesale price for injectable drugs; in 2005, urologists are being paid 106% based on the average sales price.
- Through careful negotiation of low pricing and flexible price-setting terms, it is still possible for urologists to derive profit from administration of LHRH agonists.
- In 2006, regulations will allow urologists to either continue to buy and store their own injectable drugs, or to have them delivered by a contracted agent. Whether this proves advantageous to the physician depends on the final terms of the new regulations.

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Urology Times®

FAQs about in-office injections: What you need to know

Everything you wanted to know about changes now in effect but didn t know whom to ask

Mar 1, 2005
By: Ray Painter, MD
Urology Times

Correction
In my February 2005 Urology Times article ("Reimbursement, codes for injections are new in 2005," page 36), the code given for therapeutic and diagnostic injections was wrong. G0353 is actually for intravenous injection. The correct code for intramuscular injection, diagnostic and therapeutic, is G0351. Please accept my apology for this mistake.

Also, I have some good news about therapeutic injections. The rules have been changed. If you look on AUACodingToday.com (see related article, page 4), the payment designation for this code is now A instead of T.

That means, as of Jan. 1, 2005, you can charge an office visit (if the OV is "medically necessary" and meets the definition of the -25 modifier), with a diagnostic or therapeutic injection for the first time since 1992. The -25 modifier must be attached to the E&M code.

A number of questions still surround coding and reimbursement for in-office drug injections. As a result, this article will take a slightly different approach, using a "frequently asked questions" format. I'll repeat the questions I've been asked about the new drug payments at seminars and via phone and e-mail, and attempt to give you straight answers to the best of my understanding.

You are well aware by now that the Medicare Modernization Act of 2003 changed the way physicians are paid for injectable drugs in the office. In the past, urologists were paid a percentage of the average wholesale price (AWP), whereas this year we are being paid based on average sales price (ASP). The change will have a significant financial impact on practicing urologists (see "How urologists are impacted financially," below).

Also, CMS changed the rules last year on how we can charge for office visits in conjunction with our chemotherapy injections, and the injection codes have changed. What can the practicing urologist expect this year? Below are some answers related to reimbursement and coding for the drugs themselves as well as the injection of these drugs.

What is the difference between AWP and ASP? AWP is the price provided by the pharmaceutical company for each drug prior to January 2005. This was published in the ?red book? and in many cases did not accurately reflect the price the drugs were selling for. ASP is the average price that each drug sold for in the quarter being reported.

How is ASP calculated? Each pharmaceutical company will calculate the ASP for each of its drugs on a quarterly basis, using actual sales information based on detailed and standardized rules. All drug sales, with few exceptions (eg, drugs sold to Medicaid, other government agencies, and a few

other specific categories), will be included. All sales to physicians, purchasing groups, pharmacists, and wholesalers, including all volume, cash, or other discounts will be used in the calculations. ASP will first be determined by the manufacturer's report, which includes all sales, number of units, and the price of each unit (manufacturer's ASP). Then CMS will average all manufacturers' ASP that is charged under a single "J" code according to their respective volumes to determine an ASP for that J code. For example, the ASP for leuprolide acetate (Lupron, Eligard) will be averaged to develop a single ASP for the J code J9217.

What is "least costly alternative" (LCA)? LCA is the payment methodology that allows Medicare to pay the same payment for drugs that have been determined by Medicare to be "medically equivalent," for example leuprolide (Lupron, Eligard) and goserelin acetate (Zoladex). The Medicare carrier in each state decides whether or not to pay for the drugs using the LCA methodology.

Which states are not using the LCA methodology? Those that are not currently LCA states are Illinois, Michigan, Minnesota, Wisconsin, and Montana. Also, Utah has rescinded the LCA payment methodology for 6 months, starting in January.

What can I do to change my state to a non-LCA state? Contact your Medicare carrier medical director and explain the reasons that you think it should be discontinued. AUA has presented this argument to CMS.

What will Medicare pay for leuprolide this year in a non-LCA state? The payment as published (106% of ASP) in the final payment rules for 2005 is $253.13 for J9217. Medicare will pay 80% of $253.13 for both Lupron and Eligard.

What will the government pay for a goserelin implant this year in a non-LCA state? The payment for J9202 as published is $189.79. The payment will be 80% of the published price.

What will Medicare pay for triptorelin pamoate for injectable suspension (Trelstar) this year in a non-LCA state? Triptorelin, being re-launched by Watson Pharmaceuticals in the second quarter of this year, is in a unique position. Since the drgu has been off the market for the last several quarters, it probably will not have an ASP. Therefore it will be paid using wholesale acquisition cost (WAC) methodology.

Contractually, Medicare could potentially pay a higher price according to the WAC. If Watson decided to give a cash discount, volume discount, etc., the discount would apply to the average selling price over 12 months. Therefore, contract price could continue to be lower than ASP for the next year.

What will Medicare pay for leuprolide and goserelin in an LCA state? Medicare has determined that goserelin and all forms of leuprolide injectables are medically equivalent. Therefore, it will pay equally for all three--Lupron, Eligard, and Zoladex (or drugs in that category). Medicare will pay 80% of $189.79, the published price for goserelin, which is the lowest payment of the three drugs. Currently, triptorelin is not included in the LCA payment category and therefore would not be included. However, any state could change its policy and include it in the future.

Will the payment for any of the drugs change next quarter? As long as there is competition in the marketplace and changes in the contract price that you pay for the drugs, chances are that ASPs will change each quarter for all drugs.

What can be done in the case of bladder cancer drugs, which cost more than what we're paid by Medicare? There is no good answer at this time. AUA is working on a solution and has raised the issue with the government. AUA is also exploring urologist options with group purchasing. Some physicians are thinking of sending their patients to the pharmacy, but if you do this, the patient will not be reimbursed by Medicare. Other urologists are refusing to buy, sending their patients to the hospital.

Is there a chance the government will change the rules and pay more for drugs this year? The rules allow for an exception to the ASP payment system. CMS has indicated it would take another look at the bladder cancer drugs, but has not indicated that it will pay more. I don't think there's any chance that Medicare will increase the price on LHRH agonists.

What am I being paid in 2005 for injecting LHRH agonists in the office? The national average payment by Medicare for LHRH injections has decreased from $64.07 in 2004 to $36.62.

What injection code should I use for injecting LHRH agonists this year? The new code for all LHRH injections for Medicare patients is G0356 (chemotherapeutic injection, hormonal). Therefore, this is the correct code to use for goserelin acetate (Zoladex), triptorelin pamoate (Trelstar), and leuprolide acetate (Lupron, Eligard) for Medicare patients in all states, even those that used to require you to use the therapeutic injection code. Continue to use 96400 for private insurance patients unless the payer instructs you to use the G codes.

Can I charge for the demonstration G codes each time I see a cancer patient for questioning about pain and their general condition and get paid the extra $130.00 per visit, as suggested in one of the coding newsletters? Unfortunately, you cannot charge those codes in conjunction with an intramuscular or subcutaneous injection. However, if you're giving an IV injection or infusion, you can charge the extra codes.

What injection code should I use this year for testosterone and other injections? The new code for Medicare is G0351 (therapeutic or diagnostic injection). Continue to use the CPT code 90782 for private payers.

Can I charge a nursing visit when I give an LHRH injection? No. One can no longer charge a 99211 first-level established patient visit (commonly called "the nursing code") on the same day that a chemotherapeutic administration occurs. The law changed the rules in 2004 for charging an evaluation and management service on the same day as a chemotheraputic administration (96400). This rule applies to the new Medicare code G0356 in 2005.

Can you charge for an office visit when the urologist evaluates a patient on the same day that an LHRH injection is administered? Yes, if the urologist sees the patient and provides a service that qualifies for the use of a -25 modifier and provides a higher level of service than 99211, then the E&M service can be charged by attaching the -25 modifier to the appropriate level office visit code. Be sure that your documentation reflects that the service is significant and separately identifiable from the injection and that it was medically necessary.

What happens if I switch from a 3-month to 1-month injection or a 12-month implant? The Office of Inspector General has warned physicians not to switch patients to different drug cycles for economic reasons. If you switch patients to implants or to different monthly intervals, be sure to document the medical reasons for doing this.

Can I still make a profit over 6%? Yes, the payment is for 106% over ASP, not the invoice price. The idea is to continue to buy low and sell high.

What is the best strategy for 2005? Urologists should continue to get the best price they can for the drug most appropriate for their patients, be sure the contract price is ASP or below, and be aware that the payment may change (possibly decrease) each quarter. It is advisable to be prepared to adjust purchasing contracts accordingly. Avoid long-term contracts until you know all of the options.

Will the payments change in 2006? In 2006, physicians will likely have two main options:

- Choose to continue to buy drugs and to be paid 106% of the ASP, as you are doing in 2005.
- Obtain drugs from one of the contracting agents designated by Medicare for each area that

will deliver the drugs to the office at no cost to the physician. The rules governing the agencies have not been finalized. Originally, the regulations suggested that the decision is all or nothing; if a physician chooses to continue buying drugs, then they must buy all of their drugs. If they choose to use the acquisition agent, then they must obtain all drugs through that agency. However, CMS is considering allowing physicians to continue and is accepting comments on this issue currently.
Making this choice will alleviate all charges for drugs to Medicare and will eliminate any income for storing or handling the drug. However, there are many unknowns about the new system.

How urologists are impacted financially

According to Medicare statistics, urologists received approximately 37% of their 2004 total Medicare revenues from drugs and 60% from all other services. Medicare has estimated that the change in payment for drugs will decrease the overall urology income from LHRH agonists by 38%. The overall impact will be a decrease of 14% in payments from Medicare.

This profit center last year accounted for over 30% of the "take-home pay" for some urologists. Urologists are expected to lose a majority of that income?approximately $60,000 for the average urologist.**UT**

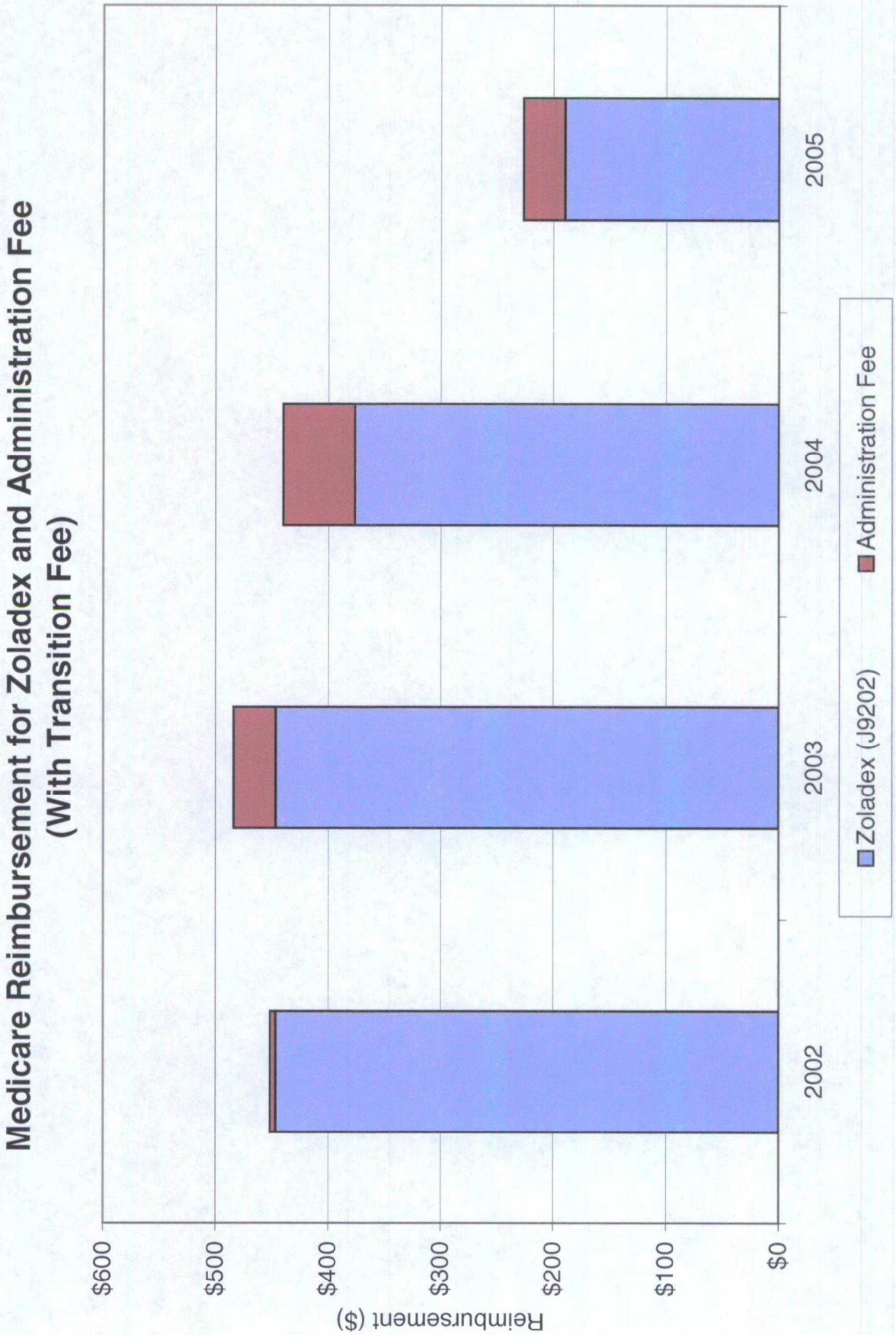
Disclaimer: The information in this column is designed to be authoritative, and every effort has been made to ensure its accuracy at the time it was written. However, readers are encouraged to check with their individual carrier or private payers for updates and to confirm that this information conforms to their specific rules.

Changes in Medicare Reimbursement for a Typical Administration of Zoladex Including Transition Fees

Year	Medicare Reimbursement Method	Medicare-Based AWP	Medicare Reimbursement for J9202 (includes copay amount)	Medicare Reimbursement for Code = 96400 (G0356 in 2005)[1]	Total Reimbursement	Change in Reimbursement from Previous Year
2002	95% awp	469.99	446.49	5.07	451.56	
2003	95% awp	469.99	446.49	37.52	484.01	32.45
2004	80% awp	469.99	375.99	64.07	440.06	-43.95
2005	1.06 asp		189.79	36.69	226.48	-213.58

Notes

1. Source: Federal Register, Vol. 69, p. 66405.

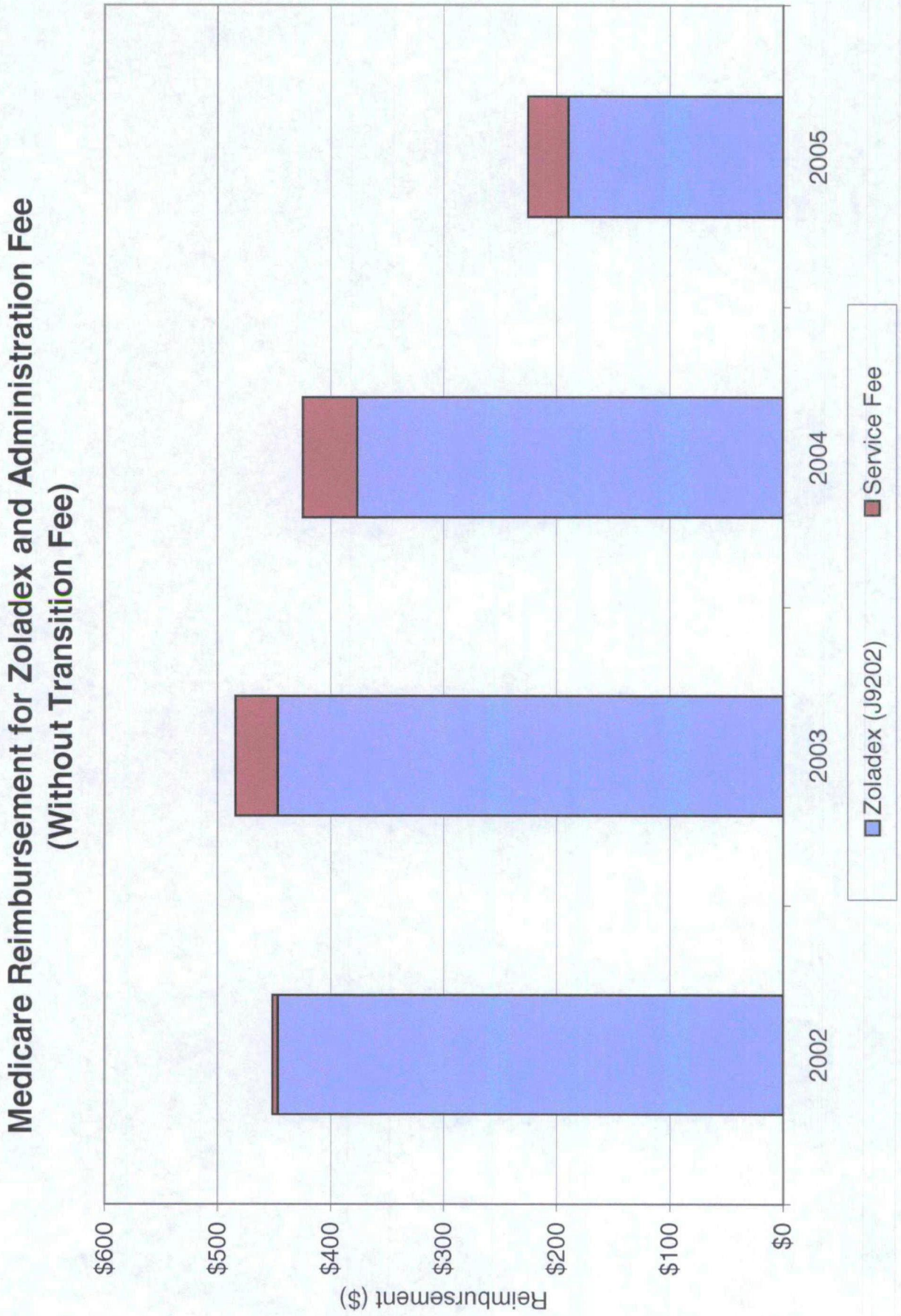

Medicare Reimbursement for Zoladex and Administration Fee
(With Transition Fee)
Reimbursement ($)
$600
$500
$400
$300
$200
$100
$0
2002
2003
2004
2005
Zoladex (J9202)
Administration Fee

Changes in Medicare Reimbursement for a Typical Administration of Zoladex Without Transition Fees

Year	Medicare Reimbursement Method	Medicare-Based AWP	Medicare Reimbursement for J9202 (includes copay amount)	Medicare Reimbursement for Code = 96400 (G0356 in 2005)[1]	Total Reimbursement	Change in Reimbursement from Previous Year
2002	95% awp	469.99	446.49	5.07	451.56	
2003	95% awp	469.99	446.49	37.52	484.01	32.45
2004	80% awp	469.99	375.99	48.54	424.53	-59.48
2005	1.06 asp		189.79	35.62	225.41	-199.12

Notes

1. Source: Federal Register, Vol. 69, p. 66406.


Medicare Reimbursement for Zoladex and Administration Fee
(Without Transition Fee)
Reimbursement ($)
$600
$500
$400
$300
$200
$100
$0
2002
2003
2004
2005
Zoladex (J9202)
Service Fee